

Claims

We claim:

1. A liposome-based parenteral composition comprising:
 - 5 (a) an effective amount of an active ingredient comprising erythropoietin or its pharmaceutically acceptable derivatives having the biological properties of causing bone marrow cells to increase production of reticulocytes and red blood cells;
 - (b) a lipidic phase comprising:
 - 10 (i) lecithin or hydrogenated lecithin;
 - (ii) optionally, a charged electropositive or electronegative lipid compound and
 - (iii) cholesterol or a derivative thereof selected from cholesterol esters, polyethylene glycol derivatives of cholesterol (PEG-
15 cholesterol), and organic acid derivatives of cholesterol; and
 - (c) a phosphate buffer.
2. The composition of claim 1 wherein the composition comprises single bilayered
20 liposomes made by preparing a solution of the lipidic phase in an alcoholic solvent and injecting the solution under pressure into the aqueous buffer solution contained in a high speed homogenizer.
3. The liposome-based formulation of claim 1, characterized in that it comprises
25 furthermore a stabilizer.
4. The liposome-based formulation of claim 3, wherein the stabilizer is glycine.
5. The liposome-based formulation of claim 1, wherein the lecithin is
hydrogenated lecithin.

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6. The liposome-based formulation of claim 1, wherein the charged electropositive or electronegative lipid compound is selected from dipalmitoyl phosphatidic acid (DPPA), di-palmitoylglycerole (DPPG), oleyl amine and stearyl amine.
- 5 7. The liposome-based formulation of claim 1, wherein the buffer is selected from sodium dihydrogen phosphate dihydrate, di-sodium hydrogen phosphate dihydrate, and mixtures thereof.
8. The liposome-based formulation of claim 1, characterized in that it furthermore
10 comprises a preserving agent.
9. The liposome-based formulation of claim 1, characterized in that it furthermore comprises an antioxidant.
- 15 10. The liposome-based formulation of claim 1, characterized in that it furthermore comprises a complexing agent.
11. The liposome-based formulation of claim 1, characterized in that it has the following composition:

| | | |
|----|------------------------------|---------------------------|
| 20 | | <u>g/100g</u> |
| | EPO or analogous compounds | 200,000 U - 1 Mill. Units |
| | Lecithin hydrogenated (Soya) | 0.5 - 5.000 |
| | Cholesterol | 0.1 - 1.000 |
| | Charged lipid | 0.05 - 0.5 |
| 25 | Ethanol | 0.5 - 5.000 |
| | Glycine | 0.0 - 1.00 |
| | Buffer | 0 to 2.0 |
| | Water | q.s ad 100.0. |

12. The liposome-based formulation of claim 1 for use as a pharmaceutical preparation for the treatment of anemia.
- 5 13. The liposome-based formulation of claim 1, characterized in that it has the following composition:

| | <u>g/100 g</u> |
|---|----------------|
| Erythropoietin | 1 Million I.U. |
| 10 Lecithin (Soya) hydrogenated | 0.500 |
| Cholesterol | 0.100 |
| DPPA-Na | 0.040 |
| Ethanol Pharma Undenatured | 0.500 |
| Sodium Dihydrogenphosphate Dihydrate | 0.1164 |
| 15 di-Sodium Hydrogen Phosphate Dihydrate | 0.2225 |
| Sodium Chloride | 0.584 |
| Water purified | 97.9371 |